

### **REMARK**

Claims 1-7 are pending in the application. Claims 1 and 7 has been amended to further define the claimed subject matter. Support for the amendment to claim 1 can be found throughout the specification and including, e.g., in paragraph 068 and Example 2. Support for the amendment to claim 7 can be found at, for example, Figures 2, 3B and 3D of the application as filed.

The Applicants submit that the amendments to the claims presented *supra* are supported by the specification as filed and published and do not add new matter. The Applicants respectfully request entry of the claims as amended.

### **REJECTION UNDER 35 USC § 112, FIRST PARAGRAPH**

Claim 7 has been rejected under 35 USC § 112, first paragraph, as allegedly lacking support in the specification. The Examiner objects to the language "wherein R' is selected from the group consisting of ... oxygen" and contends that the specification as originally filed does not provide support for the oxygen group being at position R' in the Genus A structure shown in claim 7. Applicants traverse.

The Genus A structure with an oxygen group at position R' is clearly shown in Figures 2 (the structure for iso-alpha acids), 3B and 3D of the application as filed. These structures are further identified by name either on the figure or in the brief description of the drawings section at paragraph 18.

By providing Figures 2, 3B, and 3D, Applicants submit the they have conveyed with reasonable clarity to those skilled in the art that, as of the filing date sought, they were in possession of the invention as now claimed in claim 7 including the Genus A structure with an oxygen in place of R' group. As described in M.P.E.P. §§ 2163 and 2163.02, the courts have established the standards for determining compliance with the written description requirement by indicating that

An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using

such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). (emphasis added)

Accordingly, Applications submit that Figures 2, 3B, and 3D provide the necessary information for one skilled in the art to identify the compounds of Genus A as claimed, that the specification provides support for claim 7, and that no new matter has been inserted into the claims. As such, the Applicants respectfully request withdrawal of this rejection.

#### **REJECTIONS UNDER 35 USC § 102 OVER SHAHLAI**

Claims 1 – 3 have been rejected under 35 USC § 102(e) as being anticipated by Shahlai et al (U.S. Patent 6,583,322; hereinafter Shahlai). The Examiner contends that Shahlai discloses compositions comprising reduced isoalpha acid (RIAA) and isoalpha acid (IAA) in the abstract; Figures 1 and 2; column 1, lines 14-24 and lines 60-63; and column 4, lines 2-25. The Examiner further alleges that in column 18, lines 15-45, mixtures of dihydro isoalpha acid (DHIA) and IAA at all ratios between about 1 to 99% have been disclosed. Applicants respectfully traverse this rejection for at least the following reasons.

The standard for an anticipatory reference is set forth in *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987): "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See also

Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236 (Fed. Cir. 1989)(holding that “[t]he identical invention must be shown in as complete detail as is contained in the ... claim”).

It is well established that in order for a prior art reference to amount to an inherent anticipation of a claim, all the elements of the claim must necessarily, inevitably, and always result from the prior art disclosure and would be so recognized by one of ordinary skill in the art; mere possibilities or probabilities are not sufficient. See Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264, 1269, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991); W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553-54, 220 U.S.P.Q. 303, 313-14 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984); In re Oelrich, 666 F.2d 578, 581, 212 U.S.P.Q. 323, 325-26 (C.C.P.A. 1981); Phillips Petroleum Co. v. U.S. Steel Corp., 673 F.Supp. 1278, 1295 n.12, 6 U.S.P.Q.2d 1065, 1076-77 n.12 (D. Del. 1987), ad, 865 F.2d 1247, 9 U.S.P.Q.2d 1461 (Fed. Cir. 1989); Hughes Aircraft Co. v. U.S., 8 U.S.P.Q.2d 1580, 1583 (Ct. Cl. 1988); Ex parte Levy, 17 U.S.P.Q.2d 1461, 1463-64 (B.P.A.I. 1990); Ex parte Skinner, 2 U.S.P.Q.2d 1788, 1788-89 (B.P.A.I. 1987).

Claim 1 as currently amended recites a composition for reducing PGE2 mediated inflammation comprising a reduced isoalpa acid (RIAA) and isoalpa acid (IAA) wherein the RIAA and IAA are in a ratio of about 3:1 to about 1:10. Shahlai does not teach nor suggest such a composition with that specific range of RIAA and IAA. Shahlai's disclosure is heavily focused on non-precipitating compositions of high trans to cis isomers of dihydro- (DHIA) and hexahydro- (HHIA) isoalpa acids (both being RIAA) that do not form haze or particulates upon addition to finished beer. In what appears to be a mere possibility, in the last sentence of the abstract, Shalai mentions that “[t]he high trans products described herein can be admixed with isoalpa- and tetrahydro-isoalpa acids”, not even distinguishing between the reduced and non-reduced forms of isoalpa acids. In figures 1 and 2, Shahlai illustrates the catalyzed reactions involved in the production of isomeric dihydro- and hexahydro alpha acids from isoalpa acids and

tetrahydro isoalpa acids respectively. Although the reactions in figures 1 and 2 may indicate the probability that the a residual amount of reactants may possibly remain admixed with the products, non of the figures (and in particular figure 1) suggests a mixture of isoalpa acid and dihydoro-isoalpa acid.

Applicants further disagree with the Examiner's contention that Shahlai discloses compositions of RIAA and IAA at column 1, lines 14-24 and lines 60-63. At column 1, lines 14-24, Shahlai only provides background information about various types of reduced and un-reduced isoalpa acids. There, Shahlai does not even mention that any of the isoalpa acids can possibly be mixed together. At column 1, lines 60-63, Shahlai states: "In these commercial preparations, the hop acids, and particularly 30% IA and 35% DHIA, as potassium salts at pH 10 or above in water, act as co-solvents for themselves." The phrase "In these commercial preparations" refers back to a few lines above in the same paragraph, at lines 49-53 in column 1, where Shahali describes how each of the solutions of 30% IA and 35% DHIA is sold separately. IA is commercially sold as 30% solution in water at pH 10 and DHIA is sold as 35% solution in water at pH 10.5, Shahlai states. Therefore, when reading the paragraph in entirety, from line 46 to 63 of column 1, there is no suggestion of a composition of RIAA and IAA.

Shahlai only makes general, non-specific statements that high trans to cis isomers of DHIA and HHIA of the invention can have added amounts of isoalpa- and tetrahydor-isoalpa acids. At column 4, lines 18-23, Shahlai states —as in the abstract— that "the objects of this disclosure are to provide DHIA and HHIA having a high trans to cis isomer ratio and, as a consequence, to provide [five outcomes one of which is] Non-precipitating mixtures of DHIA and/or HHIA solutions with added IA and THIA." With regard to the compatibilities of such mixtures, in Example 5, Shahlai makes the following rather unclear statement at column 18, lines 35-38, that

[m]ixtures of the DHIA and THIA and/or IA were compatible and remained clear liquids at all ratios between about 1-99%.

Here, Shahlai provides a broad range of mixing ratios without a sufficient specificity as to what acids are actually mixed at what ratios. The only specific ratio information provided in Shahlai are those presented in Table 5-1, at column 18. Out of eight mixtures (1-8) shown, none of which being a mixture of IA and DHIA, only mixtures 1, 3, and 4 disclose specific ratios of IA and THIA (a reduced isoalpha acid). However, even there, the disclosed range for THIA (40-70%) falls significantly out of the range of RIAA presently claimed (about 10-33%).

With regard to anticipation of ranges, M.P.E.P. § 2131.03 states that if the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with "sufficient specificity" to constitute an anticipation of the claims. This section further states that "if it is unclear if the reference teaches the range with sufficient specificity, the Examiner must, in this case, provide reasons for anticipation as well as a motivational statement regarding obviousness."

In this case, Shahlai neither specifically indicates the claimed ratios of the isoalpha acids and reduced isoalpha acids nor in any way suggests that the specific ratios would be advantageous in reducing PGE2 mediated inflammation. It is therefore respectfully submitted that the specific ranges of the ratios of IAA and RIAA disclosed and claimed by the Applicants are not disclosed with sufficient specificity in Shahlai to either anticipate the Applicants' invention or suggest to one skilled in the art the use thereof. Further, Applicant submit that the claimed ranges identify certain ratios having qualities (foremost synergy) not previously known or suspected. The compositions and the methods of the invention stem from the identification of synergistic ratios of reduced isoalpha acid and isoalpha acids which are neither taught nor suggested by the art cited. As such, Applicants submit that the claimed ranges reflect unexpected results and novelty over Shahlai. Applicants respectfully request that the rejection of claims 1-3 under 35 USC § 102 be withdrawn.

## **REJECTIONS UNDER 35 USC § 103 OVER TOBE**

Claims 4-7 are rejected under 35 USC § 103(a) as being unpatentable over Tobe (US Patent No. 5,604,263; hereinafter Tobe). Applicants respectfully submit that this rejection was previously addressed in the response filed November 4, 2005, where Applicants successfully distinguished the claimed invention from what is disclosed by Tobe. In the subsequent Office Action dated February 7, 2006, the Examiner considered the Applicants arguments persuasive and removed the rejection. Applicants submit that no new matter has been added to the claims since the previous rejection was addressed and that the claims 4-7 remain substantially the same as, if not narrower than, the original claims. Therefore, Applicants respectfully request that the Examiner withdraw this rejection.

## **DOUBLE PATENTING**

Claims 1 – 7 have been provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1 – 115 of copending Application Nos: 11/344,555, 11/344,556, and 11/344,557.

Claims 4 – 7 have been provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1 – 34 of copending Application No: Nos: 11/344,552, 11/344,554, and 11/403,034.

Claims 1 – 3 have been provisionally rejected under the judicially created doctrine of obvious-type double patenting as being unpatentable over claims 1 – 31 of copending Application No: 10/789,817.

The Applicants again offer to submit and accept terminal disclaimers linking any of the cited copending applications to the instant application should the instant case proceed to allowance and if the prosecuting Examiner maintains, in the copending cases cited, a rejection under the judicially created doctrine of obvious-type double patenting as being unpatentable over the instant case.

## **CONCLUSION**

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

If there are any outstanding issues that might be resolved by an interview or an Examiner's amendment, The Examiner is requested to call Applicants' attorney at the telephone number shown below.

Pursuant to 37 C.F.R. § 1.136(a)(2), the Examiner is authorized to charge any fee under 37 C.F.R. § 1.17 applicable in this instant, as well as in future communications to Deposit Account 50-1133. Furthermore, such authorization should be treated in any concurrent or future reply requiring a petition for an extension of time under 37 C.F.R. § 1.136 for its timely submission, as constructively incorporating a petition for extension of time for the appropriate time pursuant 37 C.F.R. § 1.136(a)(3) regardless of whether a separate petition is included.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 50-1133.

Respectfully submitted,  
McDERMOTT, WILL & EMERY, LLP.

Dated: December 27, 2006

By: 

Atabak R. Royae, Reg. No. 59,037  
McDERMOTT, WILL & EMERY, LLP.  
28 State Street  
Boston, Massachusetts 02109-1775  
Tel. (617) 535-4108  
Fax: (617) 535-3800